

## **REMARKS**

### **I. PRELIMINARY REMARKS**

A minor amendment has been made to the specification. Claims 1, 8 and 9 have been amended. No claims have been added. Claims 35 and 36 have been canceled. Claims 1-9, 28-34 and 37-57 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

The Advisory Action indicated that the Information Disclosure Statement ("IDS") filed on January 24, 2004 was not considered because it lacked a statement under 37 C.F.R. § 1.97(e). Given the fact that the January 24, 2004 IDS was filed before the mailing of a final Office Action (note the certificate of mailing) and was filed with the fee set forth in 37 C.F.R. § 1.17(p), applicant respectfully submits that a statement under 37 C.F.R. § 1.97(e) was not required. Nevertheless, in order to obviate the issue, applicant has re-cited the references from the January 24, 2004 IDS in the IDS being filed concurrently herewith.

### **II. CLAIMS 1-8 AND 28-36**

#### **A. The Rejections**

Claims 1-7, 28-30, 35 and 36 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of U.S. Patent No. 5,785,706 to Bednarek (the Bednarek '706 patent) and U.S. Patent No. 6,277,115 to Saadat (the Saadat '115 patent). Claims 1-8 and 28-36 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of U.S. Patent No. 5,584,872 to LaFontaine (the LaFontaine '872 patent), U.S. Patent No. 5,792,140 to Tu (the Tu '140 patent) and the Saadat '115 patent.

As claims 35 and 36 have been canceled, it is respectfully submitted that the rejections thereof have been rendered moot. The rejections of the remaining claims

under 35 U.S.C. § 103 are respectfully traversed. Reconsideration thereof is respectfully requested.

## **B. The Claimed Combinations**

Independent claim 1 calls for a combination of elements comprising “a shaft,” “a plurality of energy transmission devices supported on the shaft,” “a tissue cooling apparatus supported on the shaft including an outer member positioned about the plurality of energy transmission devices such that a continuous fluid transmission space is defined therebetween having an inlet and an outlet” and “a drainage tube, **extending distally from the distal portion of the shaft**, that conveys fluid passing through the fluid transmission space outlet away from the tissue.” Claims 2-8 and 28-34 depend from independent claim 1 and the combinations defined thereby include, *inter alia*, the elements recited in independent claim 1.

## **C. Discussion Concerning the Rejection Based on the Proposed Combination of the Bednarek ‘706 and Saadat ‘115 Patents**

The Bednarek ‘706 patent discloses a catheter and introducer apparatus. There are a variety of differences between the respective combinations defined by claims 1-7 and 28-30 and the apparatus disclosed in the Bednarek ‘706 patent. For example, the Bednarek ‘706 patent fails to teach or suggest a combination of elements including “a drainage tube, **extending distally** from the distal portion of the shaft,” as recited in independent claim 1. To the contrary, and as illustrated in Figure 8, the Bednarek introducer includes a plurality of ventilation openings 22 “that permit fluids to flow in and out.” [Column 9, lines 31-40.]

The Saadat ‘115 patent discloses various devices that employ a pump 42 to recapture conductive fluid that is emitted by a porous electrode 22. Referring to Figure 1, the conductive fluid may be sucked into a withdrawal conduit 40 by way of an intake opening 44. [Column 3, lines 25-39.] Alternatively, as illustrated in Figure 5, the fluid may be sucked into an outer conduit 60 by way of a withdrawal outlet 62. Even

assuming for the sake of argument that there was some reason to combine the respective teachings of the Bednarek '706 and Saadat '115 patents, and that either of the Saadat conduits 40 and 60 could be considered a "drainage tube," the Saadat conduits **extend proximally** from the distal portion of the associated apparatus, **not distally** as recited in independent claim 1.

As the Bednarek '706 and Saadat '115 patents fail to teach or suggest the combination of elements recited in independent claim 1, whether viewed alone or in combination, applicant respectfully submits that the rejection of claims 1-7 and 28-30 under 35 U.S.C. § 103 should be withdrawn.

**D. Discussion Concerning the Rejection Based on the Proposed Combination of the LaFontaine '872, Tu '140 and Saadat '115 Patents**

The LaFontaine '872 patent discloses a variety of different RF energy treatment devices. Each of the treatment devices includes a single electrode and a structure, within which the electrode is recessed, for conveying an electrolytic fluid through the electrode to the tissue being treated. The Tu '140 patent discloses a catheter 2 including a tip electrode 12 with a plurality of hollow needles 13 and a band electrode 14 with a plurality of hollow needles 15. Each of the needles defines a passage 20 and an outlet port 21, which direct fluid from the interior of the catheter 2, through the electrodes 12 and 14, and to the tissue surface (as well as to the surface of the electrodes). In contrast to the invention defined by independent claim 1, the LaFontaine '872 and Tu '140 patents fail to teach or suggest a combination of elements including "**a drainage tube, extending distally** from the distal portion of the shaft."

The Saadat '115 patent fails to remedy the above-identified deficiency in the LaFontaine '872 and Tu '140 patents. As discussed in Section II-C, the Saadat conduits 40 and 60 **extend proximally** from the distal portion of the associated apparatus, **not distally**.

Accordingly, even assuming for the sake of argument that there was some reason to combine the respective teachings of the Bednarek '706, Tu '104 and Saadat '115 patents, the proposed combination clearly fails to result in the combination of

elements recited in claim 1. Applicant respectfully submits, therefore, that the rejection of claims 1-8 and 28-34 under 35 U.S.C. § 103 should be withdrawn.

### **III. CLAIM 9**

#### **A. The Rejections**

Claim 9 has been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Bednarek '706 patent and the Saadat '115 patent. Claim 9 has also been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the LaFontaine '872 patent, the Tu '140 patent and the Saadat '115 patent. The rejections under 35 U.S.C. § 103 are respectfully traversed. Reconsideration thereof is respectfully requested.

#### **B. The Claimed Combination**

Independent claim 9 calls for a combination of elements comprising "a shaft," "a plurality of energy transmission devices," "a tissue cooling apparatus ... fluid transmission space is defined therebetween having an inlet and an outlet," "a drainage tube" and "a fluid supply line associated with the inlet and supported *on the exterior of the shaft.*"

#### **C. Discussion Concerning the Rejection Based on the Proposed Combination of the Bednarek '706 and Saadat '115 Patents**

The Bednarek '706 patent discloses a catheter and introducer apparatus. The catheter supports a plurality of electrodes. In contrast to the invention defined by independent claim 9, the exterior of the Bednarek catheter does not support a "fluid supply line." The Saadat '115 patent, which discloses fluid supply conduits within the shaft 14, fails to remedy the deficiency in the Bednarek '706 patent.

As the Bednarek '706 and Saadat '104 patents fail to teach or suggest the combination of elements recited in independent claim 9, whether viewed alone or in combination, applicant respectfully submits that the rejection of claim 9 under 35 U.S.C. § 103 should be withdrawn.

**D. Discussion Concerning the Rejection Based on the Proposed Combination of the LaFontaine '872, Tu '140 and Saadat '115 Patents**

In contrast to the invention defined by independent claim 9, each of the RF energy treatment devices disclosed in the LaFontaine '872 patent includes an internal fluid supply lumen 40. The catheter disclosed in the Tu '140 patent also includes an internal fluid supply lumen. The Saadat '115 patent discloses fluid supply conduits within the shaft 14.

Accordingly, even when improperly combined in the manner proposed in the Office Action, the LaFontaine '872, Tu '140 and Saadat '115 patents fail to teach or suggest the combination defined by independent claim 9. The rejection of claim 9 under 35 U.S.C. § 103 should, therefore, be withdrawn.

**IV. CLAIMS 37-48**

**A. The Rejections**

Claims 37-48 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the LaFontaine '872 patent, the Tu '140 patent and U.S. Patent No. 5,797,903 to Swanson (the Swanson '903 patent). The rejections under 35 U.S.C. § 103 are respectfully traversed. Reconsideration thereof is respectfully requested.

## B. The Claimed Combinations

Independent claim 37 calls for a combination of elements comprising “a shaft defining a distal end and a proximal end,” “a plurality of energy transmission devices supported on the shaft” and “a **tissue cooling apparatus** supported on the shaft including an outer member, configured to permit ionic transfer while substantially preventing fluid perfusion therethrough, positioned about the plurality of energy transmission devices such that a continuous fluid transmission space is defined therebetween having an inlet and an outlet.” Claims 38-48 depend from independent claim 37 and the combinations defined thereby include, *inter alia*, the elements recited in independent claim 37.

## C. Discussion Concerning the Rejection Based on the Proposed Combination of the LaFontaine ‘872, Tu ‘140 and Swanson ‘903 Patents

The rejection under 35 U.S.C. § 103 based on the proposed combination of the LaFontaine ‘872, Tu ‘140 and Swanson ‘903 patents is improper for a variety of reasons. Most notably, it completely ignores what the references actually teach and improperly “pick[s] and choose[s] among isolated disclosures in the prior art to deprecate the claimed invention.” *In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

Each of the treatment devices disclosed in the LaFontaine ‘872 patent includes a single electrode and a structure, within which the electrode is recessed, for conveying an electrolytic fluid through the electrode to the tissue being treated. Conveying electrolytic fluid to the tissue serves two primary purposes – **(1) establishing an electrical path** from the electrode to the tissue, and **(2) cooling the tissue** so that deeper lesions may be formed. [Column 8, lines 13-32.] Referring to Figure 5, the RF treatment device 78 illustrated therein includes an expandable member 80 with perforations 96. The expandable member 80 is carried on the distal end of a catheter tube 84, which has a single lumen 40 (i.e. the catheter tube is designed for one directional flow). An electrode 89 with a distal opening and apertures 92 is also supported on the distal end of the

catheter tube 84. Conductive fluid flows through the catheter tube 84 and electrode 89, into expandable member 80, and through the perforations 96 to establish an electrical path between the electrode 89 and tissue.

In contrast to the invention defined by independent claim 37, the LaFontaine '872 patent clearly lacks "a plurality of energy transmission devices" as well as "a tissue cooling apparatus ... configured to permit ionic transfer while substantially preventing fluid perfusion therethrough."

The Office Action relies on the Tu '140 patent, which discloses a tip electrode 12 and a band electrode 14, to remedy the "a plurality of energy transmission devices" deficiency in the LaFontaine '872 patent. The Office Action states that it would have obvious to place "more than one energy transmitting device" inside the LaFontaine expandable member 80 in order to "provide more precise means through selective application for applying energy to targeted tissue." [Office Action at page 5.] There are a variety of errors associated with this statement. Most notably, the statement is not supported by Tu '140 patent. Nothing in the Tu '140 patent even remotely suggests placing more than one electrode *inside* an expandable member that is filled with conductive fluid. Nor is there any support for the proposition that, in the context of an expandable member that allows fluid to pass therethrough, "more than one energy transmitting device" inside the expandable member is "more precise" than a single energy transmitting device.<sup>1</sup> For this reason alone, the rejection under 35 U.S.C. § 103 is improper.

Turning to the other deficiency in the LaFontaine '872 patent, i.e. the failure to teach or suggest "a tissue cooling apparatus ... configured to permit ionic transfer while substantially preventing fluid perfusion therethrough," the Office Action looks to the Swanson '903 patent to fill in the gaps. Applicant respectfully submits that it fails to do so.

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<sup>1</sup> To the extent that the above-quoted statement on page 5 was intended to convey that the Examiner has taken "judicial notice" with respect to knowledge generally available in the art, applicant hereby traverses and requests that the Examiner provide an affidavit in accordance with MPEP § 2144.03 and 37 C.F.R. § 1.104(d)(2) to that effect. The affidavit should set forth the facts upon which the Examiner's conclusions regarding the knowledge available in the art are based. Otherwise, applicant

The Swanson '903 patent discloses a tissue heating device that includes a catheter tube 12, an inflatable body 22 that permits ionic transfer and prevents fluid perfusion, and an electrode 30 within the inflatable body. During use, the inflatable body is filled with conductive fluid. Energy from the electrode 30 that passes through the conductive fluid also passes through the inflatable body because the inflatable body permits ionic transfer.

The Office Action indicates at page 6 that the modified LaFontaine expandable member 80 would **prevent fluid perfusion**. However, it is precisely this fluid perfusion that allows the LaFontaine expandable member 80 to cool tissue. The purportedly obvious modification would also eliminate the perforations 96, given that there would be no reason to have perforations which allow the fluid perfusion that the purportedly obvious modification was intended to prevent. Thus, not only would the purportedly obvious modification eliminate one of the elements called for in claim 37 (i.e. the "outlet"), the modification would impermissibly prevent the LaFontaine treatment device 78 from performing one of its intended functions, i.e. cooling tissue. [See MPEP § 2143.01 – proposed modifications cannot "render the prior art unsatisfactory for its intended purpose" and/or "change the principle of operation of a reference."]

In view of the foregoing, applicant respectfully submits that the LaFontaine '872, Tu '140 and Swanson '903 patents fail to teach or suggest the combination of elements recited in independent claim 37, whether viewed alone or in combination, and that the rejection of claims 37-48 under 35 U.S.C. § 103 should be withdrawn.

## V. CLAIMS 49-57

### A. The Rejections

Claims 49-51, 55 and 56 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Bednarek '706 patent and the Saadat '115 patent. Claims 49-57 have been rejected under 35 U.S.C. § 103 as being

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respectfully requests that the Examiner provide a prior art reference which shows that the claimed invention would have been obvious.



unpatentable over the combined teachings of the LaFontaine '872 patent, the Tu '140 patent and the Saadat '115 patent. The rejections under 35 U.S.C. § 103 are respectfully traversed. Reconsideration thereof is respectfully requested.

## **B. The Claimed Combinations**

Independent claim 49 calls for a combination of elements comprising "a shaft defining an exterior, a distal end and a proximal end," "a **plurality of energy transmission devices** supported on the shaft" and "a **tissue cooling apparatus, fixedly secured around the exterior of the shaft**, including an outer member positioned about the plurality of energy transmission devices such that a continuous fluid transmission space having an inlet and an outlet is defined between the tissue cooling apparatus and the exterior of the shaft." Claims 50-57 depend from independent claim 49 and the combinations defined thereby include, *inter alia*, the elements recited in independent claim 49.

## **C. Discussion Concerning the Rejection Based on the Proposed Combination of the Bednarek '706 and Saadat '115 Patents**

There are a variety of differences between the respective combinations defined by claims 49-51, 55 and 56 and the apparatus disclosed in the Bednarek '706 patent. For example, even assuming for the sake of argument that the Bednarek introducer is a "tissue cooling apparatus," the introducer is **not fixedly secured** to the electrode supporting catheter, as called for in independent claim 49. To the contrary, the Bednarek apparatus is specifically designed for the electrode supporting catheter **to be movable** within the introducer.

Turning to the other reference in the proposed combination, the Office Action does not indicate how the Saadat '115 patent would have been relevant to claims 49-51, 55 and 56. The Office Action refers only to the Saadat drainage tube 40 (Office Action at page 3) despite the fact that a "drainage tube" is not recited in claims 49-51, 55 and 56. Nevertheless, to the extent that the Office Action did actually intend to apply the Saadat

'115 patent to claims 49-51, 55 and 56, there is nothing in the Saadat '115 patent that even remotely suggests modifying the Bednarek apparatus in such a manner that the introducer would be fixedly secured to the catheter.

As the Bednarek '706 and Saadat '115 patents fail to teach or suggest the combination of elements recited in independent claim 49, whether viewed alone or in combination, applicant respectfully submits that the rejection of claims 49-51, 55 and 56 under 35 U.S.C. § 103 should be withdrawn.

**D. Discussion Concerning the Rejection Based on the Proposed Combination of the LaFontaine '872, Tu '140 and Saadat '115 Patents**

The LaFontaine '872 patent does not teach or suggest the use of "a plurality of energy transmission devices" that are located within "a tissue cooling apparatus .. including an outer member positioned about the plurality of energy transmission devices such that a continuous fluid transmission space having an inlet and an outlet is defined between the tissue cooling apparatus and the exterior of the shaft." To the contrary, the LaFontaine RF treatment device 78 includes a single electrode 89. The Tu '140 patent fails to remedy this deficiency. As noted in Section IV-C above, nothing in the Tu '140 patent even remotely suggests placing more than one electrode *inside* an expandable member that is filled with conductive fluid.

Turning to the third reference in the proposed combination, the Office Action does not indicate how the Saadat '115 patent would have been relevant to claims 49-57. The Office Action only refers to the Saadat drainage tube 40 (Office Action at page 5) despite the fact that claims 49-57 do not require a "drainage tube." Nevertheless, to the extent that the Office Action did actually intend to apply the Saadat '115 patent to claims 49-57, there is nothing in the Saadat '115 patent that would have even remotely suggested the use of "a plurality of energy transmission devices" within the LaFontaine expandable member 80.

As the LaFontaine '872, Tu '140 and Saadat '115 patents fail to teach or suggest the combination of elements recited in independent claim 49, whether viewed alone or in

combination, applicant respectfully submits that the rejection of claims 49-57 under 35 U.S.C. § 103 should be withdrawn.

## VI. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

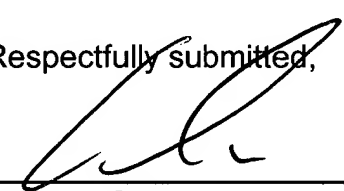
If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

6/25/01  
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Respectfully submitted,

  
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